In order to provide effective healthcare to the rural population throughout the country with special focus on18 States with poor health indicators and weak health infrastructure, the Government has launched the National Rural Health Mission in April, 2005. The Mission adopts a synergistic approach by relating health to determinants of good health and the main objective is to provide accessible, affordable, accountable and reliable health care especially to the poor and vulnerable sections of the population. Further, the gaps in the existing scenario of rural health care are being addressed through involvement of the community, the Panchayati Raj Institutions and other non-governmental organizations. An accredited social health activist will act as a link between the community and the healthcare system.

**Clinical trial of drugs**

498. SHRI JANARDHANA POOJARY: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is proposed to set up a Central Drug Authority of India (CDAI) to equip the drug regulator with enough resources;

(b) if so, the details in this regard;

(c) whether it is a fact that a number of drugs without following the Good Manufacturing Practice, proper clinical trials and also spurious drugs are being sold in the market across the country involving even critical life saving drugs; and

(d) if so, the details with number of such cases detected and the action taken during the last three years?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) Yes, Sir.

(b) The proposed Central Drug Authority of India (CDAI) will be an autonomous body under MOH&FW with ten divisions dealing with specific subjects.

(c) Drugs are being approved in the country, based on Safety, Efficacy and Quality Control data furnished by the applicant as per Drugs and Cosmetics Rules. The Drugs and Cosmetics rules are continuously

amended to meet the global standards. Schedule M (Good Manufacturing Practices and Requirement of Premises, Plan and Equipment for pharmaceutical products) and M 1 (Requirement of Factory premises for manufacture of Homoeopathic preparations), Schedule Y (Requirements and Guidelines for import and/or Manufacture of New Drugs for Sale or to undertake Clinical Trials) have been revised and Schedule L1 (Good Laboratory Practices) is being incorporated in Drugs and Cosmetics Rules. The sale of drugs as per the provisions of Drugs and Cosmetics Act & Rules is controlled and monitored by the State Drugs Controller wherein the wholesale and retail sale within stipulated conditions mentioned therein are required for selling the drugs. The Drugs Inspectors appointed by the State and Centre draw samples from the retail and wholesale outlets. The sample of drugs drawn by Drugs Inspectors are tested at Central and State Drugs Control Laboratories.

(d) The information received from State Drugs Control Authorities regarding spurious drugs in the last three years is furnished below:

| Year | No. of sample tested | No. of Drugs declared Spourious | No. of Prosecution launched |
|---|---|---|---|
| 2003-2004 | 40,862 | 118 | 570 |
| 2004-2005 | 49,2.87 | 144 | 373 |
| 2005-2006 | 32,194 | 86 | 440 |

**Malaria control in Orissa**

499. SHRI B. J. PANDA:
MS. PRAMILA BOHIDAR:
SHRI SURENDRA LATH:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government are aware that incidence of malaria is the highest in Orissa State as per a study of the Regional Medical Research Centre (RMRC); and

(b) if so, what is the action plan of Government to help this backward, cash-strapped State both financially and physically to control this menace?